



Office for Human Research Protections  
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October 30, 2001

Peder J. Estrup  
Dean of Graduate School and Research  
Brown University  
Graduate School  
Box 1867  
Providence, RI 02912

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)  
M-1411**

**Research Project: Learning Disabilities: Symptom Permanence and Consequences  
Principal Investigator: Lewis Lipsitt  
HHS Project Number: 5 R01 NS35208**

**Research Project: High-Risk Behaviors and the Prevalence of STD's among  
Women Prisoners at the Women's State Penitentiary in Metro Manila  
Principal Investigator: Kenneth Mayer  
HHS Project Number: 3 D43 TW00237**

Dear Dr. Estrup:

The Office for Human Research Protections (OHRP) has received your October 9, 2001 response to concerns regarding Brown University's (Brown) corrective actions for non-compliance in research involving prisoners as subjects. Based on this response, OHRP makes the following observations:

- (1) OHRP acknowledges that the "High-Risk Behaviors" study was completed in 1997, several years before OHRP made its determinations.
- (2) OHRP acknowledges that the "Learning Disabilities" study is ongoing but no longer includes the participation of prisoner subjects and therefore does not need to be certified

to the Secretary of Health and Human Services. In addition, although the grant application was never reviewed by the Institutional Review Board (IRB), the grant for this project expired over a year ago. However, OHRP acknowledges the Brown IRB's plans to review the expired grant at the next continuing review of the project, in February of 2002.

Based upon this information, OHRP has determined that Brown's implementation of corrective actions is adequate. OHRP anticipates no further OHRP involvement in this matter.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me if you have any questions.

Sincerely,

Kristina C. Borrer, Ph.D.  
Compliance Oversight Coordinator  
Division of Compliance Oversight

cc: Dr. Thomas K. Wunderlich, Brown  
Dr. Dan Brock, Chairperson, IRB, Brown  
Ms. Dorinda E. Williams, IRB Administrator, Brown  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. James F. McCormack, FDA  
Dr. John Mather, VA  
Dr. Greg Koski, OHRP  
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Ms. Freda Yoder, OHRP